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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/892,695	07/15/97	GRAY	J 023070068930

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EXAMINER	
JOHNSON, N	
ART UNIT	PAPER NUMBER
1642	25

DATE MAILED: 02/07/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on Election of 6/11/99, Sep Resp of 10/18/99.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 ~~month(s)~~, or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-47 is/are pending in the application.

Of the above, claim(s) 1-25, 29-36, 39-40, 42-47 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 26-28, 37-38, 41 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5 (filed 10/20/97) and 6 (filed 11/17/97)

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

1. The Election filed December 23, 1998 (Paper No. 12) in response to the Office Action of November 18, 1998 (Paper No. 10) is acknowledged and has been entered. Claims 1-47 are pending in the application and are currently under prosecution.

2. Upon review and reconsideration and in view of Applicant's Remarks, the previous restriction requirement is vacated as it is clear from the Remarks that the sequences of SEQ ID Nos 2-13 are not related in either structure or function.

3. It is noted that the claims 1, 26, 42 and 44 recite improper Markush groups because the sequences disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods. The above embodiments should be set out as separate claims.

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group I. Claims 1-25 are drawn to an isolated nucleic acid molecule comprising a polynucleotide which specifically hybridizes to a sequence, classified in Class 536, subclass 23.1.

Group II. Claims 26-41 are drawn to a method of screening for neoplastic cells and for identifying mutations comprising contacting a nucleic acid with a polynucleotide probe, classified in Class 435, subclass 6.

Group III. Claims 42-43 are drawn to a method of screening for neoplastic cells comprising contacting a polypeptide antigen encoded by a

specified polynucleotide sequence with an antibody that specifically binds to said antigen, classified in Class 435, subclass 7.1.

Group IV. Claim 44 is drawn to a method of inhibiting the pathological proliferation of cancer cells comprising inhibiting the activity of a gene product having a subsequence which hybridizes under stringent conditions to a recited sequence , classified in Class 242, subclass 130.1 and Class 514, subclass 44.

Group V. Claims 45-46 are drawn to a method comprising detecting the overexpression of a protein encoded in a 20q13 amplicon wherein the protein is ZABC1 classified in Class 435, subclass 7.1.

Group VI. Claims 45 and 47 are drawn to a method comprising detecting the overexpression of a protein encoded in a 20q13 amplicon wherein the protein is 1b1 classified in Class 435, subclass 7.1.

5. It is noted that Group I is drawn to 11 separate and distinct isolated nucleic acid molecules comprising polynucleotide sequences having a subsequence which hybridizes under stringent conditions to a sequence represented by SEQ ID Nos 2-10 and 12-13 and that in regard to each embodiment there is no disclosed relationship between the molecules and since no particular physiological correlation has been made between the molecules, the 11 nucleic acid molecules are separate inventions and are not obvious one over the other and a separate and distinct search must be made for each. The separate inventions of Group I are (a) SEQ ID NO: 2 (claims 1 and 2-3), (b) SEQ ID NO: 3 (claims 1 and 4-5), (c) SEQ ID NO:4 (claims

1 and 6-7), (d) SEQ ID NO: 5 (claims 1 and 8-9), (e) SEQ ID NO: 6 (claims 1 and 10-11), (f) SEQ ID NO: 7 (claims 1 and 12-13), (g) SEQ ID NO: 8 (claims 1 and 14-15, (h) SEQ ID NO: 9 (claims 1 and 16-17) and SEQ ID NO: 10 (claims 1 and 18-19, (I) SEQ ID

6. It is noted that Groups II-IV are drawn to 13 separate and distinct embodiments of the claimed methods represented by SEQ ID Nos 1-13 and that in regard to each embodiment there is no disclosed relationship between the embodiments and since no particular physiological correlation has been made between the nucleic acid molecules, the methods using the 13 nucleic acid molecules are separate inventions and are not obvious one over the other and a separate and distinct search must be made for each.

The separate inventions of Group II are drawn to embodiments reciting (a) SEQ ID NO: 1 (claims 26 and 29), (b) SEQ ID NO: 2 (claims 26 and 30), (c) SEQ ID NO:3 (claims 26 and 31), (d) SEQ ID NO: 4 (claims 26 and 32), (e) SEQ ID NO: 5 (claims 26 and 33), (f) SEQ ID NO: 6 (claims 26 and 34), (g) SEQ ID NO: 7 (claims 26 and 35), (h) SEQ ID NO: 8 (claims 26 and 36), (I) SEQ ID NO: 9 (claims 26 and 37) and SEQ ID NO: 10 (claims 26 and 38), (j) SEQ ID NO: 12 (claims 26 and 39), (k) SEQ ID NO: 13 (claims 26 and 40). Claim 41 will be examined with the elected invention.

The separate inventions of Group III are drawn to embodiments reciting a) SEQ ID NO: 1, (b) SEQ ID NO: 2, (c) SEQ ID NO:3, (d) SEQ ID NO: 4, (e) SEQ ID NO: 5, (f) SEQ ID NO: 6, (g) SEQ ID NO: 7, (h) SEQ ID NO: 8, (I) SEQ

ID NO: 9 and SEQ ID NO: 10, (j) SEQ ID NO: 12, (k) SEQ ID NO: 13 all of claim 42. Claim 43 will be examined with the elected invention.

The separate inventions of Group IV are drawn to embodiments reciting (a) SEQ ID NO: 1, (b) SEQ ID NO: 2, (c) SEQ ID NO:3, (d) SEQ ID NO: 4, (e) SEQ ID NO: 5, (f) SEQ ID NO: 6, (g) SEQ ID NO: 7, (h) SEQ ID NO: 8, (I) SEQ ID NO: 9 and SEQ ID NO: 10, (j) SEQ ID NO: 12, (k) SEQ ID NO: 13, all of claim 44.

7. The inventions are distinct, each from the other because of the following reasons:

Each of the Inventions of Group I as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

Each of the Inventions of Groups II-VI are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

Inventions of Groups I and II/ IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the nucleic acid products as claimed can be used in a materially

different process such as expressing the polypeptide encoded by the nucleic acid molecule.

The inventions of Groups I and III/V/VI are not at all related because the nucleic acid of Group I is not used in any of the methods of Group III/V/VI.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

9. Applicant is required to elect a single invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention; the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in

order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

12. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

13. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar

January 26, 1999